UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK

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JEANINE SORTISIO and STEVEN R. SORTISIO

Plaintiffs

vs.

**Civil No. 09 CV 0176A**

PETER ACCETTA, M.D.,
SUSAN M. PETERSON, RPA-C,
ASTELLAS PHARMA US, INC., and
NOVARTIS PHARMACEUTICALS CORPORATION

Defendants

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# MEMORANDUM OF LAW

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BROWN CHIARI, LLP
**Attorneys for Plaintiffs**
5775 Broadway
Lancaster, New York 14086
(716) 681-7190

## PRELIMINARY STATEMENT

This Memorandum is response to defendant Astellas' objections to the Report & Recommendation of Magistrate Judge Hugh B. Scott pertaining to Plaintiff's Motion to Remand.

The Plaintiffs respectfully submit that this Court should adopt the Recommendation's conclusion that the Plaintiffs' motion be granted.

## ARGUMENT

### POINT I: FEDERAL SUBJECT MATTER JURISDICTION DOES NOT EXIST

As this Court is aware, the entire basis for Defendant Astellas' removal petition was based exclusively on federal question jurisdiction.

In so doing, the Defendant set forth a severely misconstrued and stretched interpretation of Plaintiffs' Complaint. Its arguments in response to Plaintiffs' motion further provided a misplaced use of the cited authorities and an inaccurate representation of the state of the prevailing law with respect to the issues in dispute. Defendant's objections to the Report and Recommendation exhibit the same deficiencies.

Accordingly, it is respectfully submitted that the Report and Recommendation properly concluded based upon that the facts and circumstances of this case, as well as settled authority, that federal question jurisdiction is not present in this matter.

As an initial matter, the Defendant's use of *Grable & Sons Metal Products v. Darue Engineering & Manufacturing*, 545 U.S. 308, 125 S.Ct. 2363 (2005) in its attempt to widen the scope of federal jurisdiction is not an accurate depiction of the Court's findings as it relates the facts of the case at bar.

In fact, the *Grable*, and subsequent decisions, have been clear that federal question jurisdiction should be narrowly applied in such circumstances. The Court in *Grable* cited with approval the Court's prior decision in *Merrell Dow Pharmaceuticals v. Thompson*, 478 U.S. 804, 106 S.Ct. 3229, 92 L.Ed.2d 650 (1986) and noted considerations in the application of federal question jurisdiction:

> The Court saw the missing cause of action not as a missing federal door key, always required, but as a missing welcome mat, required in the circumstances, when exercising federal jurisdiction over a state misbranding action would have attracted a horde of original filings and removal cases raising other state claims with embedded federal issues. For if the federal labeling standard without a federal cause of action could get a state claim into federal court, so could any other federal standard without a federal cause of action. And that would have meant a tremendous number of cases…One only needed to consider the treatment of federal violations generally in garden variety state tort law. "The violations of federal statutes and regulations is commonly given negligence per se effect in state tort proceedings."(citations omitted)…A general rule of exercising federal jurisdiction over state claims resting on federal mislabeling and other statutory violations would thus have heralded a potentially enormous shift of traditionally state cases into federal courts. Expressing concern over the "increased volume of federal litigation," and noting the importance of adhering to "legislative intent," *Merrell Dow* thought it improbable that the Congress, having made no provision for a federal cause of action, would have meant to welcome any state-law case implicating federal law "solely because the violation of the federal statute is said to [create] a rebuttable presumption of [negligence] under state law. (citations omitted). In this situation, no welcome mat meant keep out. *Merrell Dow*'s analysis thus fits within the framework of examining the importance of having a federal forum for the issue, and the consistency of such a forum with Congress's intended division of labor between state and federal courts. *Grable* at 318.

The Supreme Court further noted in the more recent case of *Empire Healthchoice Assurance v. McVeigh*, 547 U.S. 677, 701, 126 S.Ct. 2121 (2006), "*Grable* emphasized that it takes more than a federal element to 'to open the 'arising under' door." (citations omitted) in finding the lack of federal jurisdiction under the "**slim** category that *Grable* exemplifies" (emphasis added).

The Court's findings in above cases clearly do not support extending federal question in the manner purported by the Defendant in the case at bar.

The Plaintiffs' complaint pleads only causes of action and claims for damages for negligence, express and implied warranties and strict products liability pursuant to New York State law. The Defendant relied entirely on a severely misconstrued interpretation of just one paragraph of the Plaintiffs' complaint under its negligence cause of action as its justification for its petition. The Defendant's arguments grossly stretched the plain language of paragraph 13 of the complaint in attempting to claim that the paragraph states a reliance on a demonstration a violation of the drug approval process with the Food and Drug Administration as the only basis of the entire action. However, a complete reading of the complaint makes evident that Plaintiffs allege potential violations as a merely one of the circumstances underlying its state law claims.

The paragraph at issue is merely one of multiple paragraphs in the second cause of action which describes Plaintiffs' negligence claims against the Defendant. A full reading of this section makes clear that the paragraph mentioned is only one of three paragraphs setting forth Plaintiffs' theories which generally frame the issues of their cause of action for negligence (See paragraphs 14 and 15). See *Broder v. Cablevision Systems Corporation*, 418 F3d 187 (2nd Cir. 2005) ("Where a federal issue is present as only one of multiple theories that could support a particular claim…this is insufficient to create federal jurisdiction."(citations omitted)). Paragraph 13 is the only time that the Food and Drug Administration is referenced in the Plaintiff's complaint.

The Defendant also claimed that paragraph 13 somehow set forth a separate causes of action for fraud and improper claim which again is another gross interpretation and exaggeration

of the language of Plaintiffs' complaint. A claim for fraud is separate and distinct with its own requirements for the claiming and demonstration of such a cause of action. The face of the Plaintiffs' complaint sets forth no claims or claim for damages on a cause of action for fraud. Furthermore, even under this contorted interpretation of paragraph 13, a fraud claim, in and of itself does not demonstrate the presence of federal jurisdiction.

In addition, under *Merrell Dow* it is settled that Congress did not intend to create a private remedy for violations of the FDCA. Plaintiffs' complaint claims no cause of action or the seeking of remedies under the FDCA nor could it properly under *Merrell Dow*. Furthermore, proof of improperly obtained approvals of the products by the Food and Drug Administration is not required for Plaintiff's state law causes of action to prevail. Rather, the Plaintiffs allege potential violations as a merely one of the circumstance underlining its state law claims.

In this regard, it is respectfully submitted that the Report and Recommendation properly found *Caggiano v. Pfizer, Inc.*, 384 F.Supp.2d 689 (S.D.N.Y. 2005) to be persuasive authority for not extending federal jurisdiction to this matter.

The case at bar is analogous to the circumstances in *Caggiano*. The defendants in that case claimed federal question jurisdiction under similar circumstances where the plaintiffs had noted violations of the FDCA in their complaint. As noted by the Court:

> "These contextual allegations, however, are not enough to confer federal question jurisdiction. Where no federal claim has been pleaded, a case only 'arises under' federal if a plaintiff's 'right to relief under state law requires resolution of a substantial question of federal law. the factual allegations set forth in the complaint state claims under New York law regardless of whether any federal law has been violated…put another way, a jury could find defendants liable on each and every one of the eight claims without being required to determine whether any federal law had been violated. That facts alleged may also constitute violations of federal law…is neither here nor there." (citations omitted).

The Court further concluded, "absent special circumstances, there is no federal question over garden-variety state-law claims 'resting on mislabeling and other statutory violations.'"(citations omitted). Id. at 691. *Elmira Teachers' Association v. Elmira City School District*, 2006 WL 240552 (W.D.N.Y.); *Cuomo v. Dell, Inc.*, 514 F.Supp.2d 397 (N.D.N.Y. 2007).

Unlike *Caggiano*, the cases substantially relied upon by the defendant in its arguments are notably distinguishable from the case at bar. For example in *In re: Zyprexa Products Liability Litigation*, 375 F.Supp.2d 170 (E.D.N.Y. 2005), that case involved an action by a state government which involved attempting to recoup federal funds that necessarily implicated federal funding provisions involving Medicaid which the Court found was "more federally oriented" than *Merrill Dow*, a case brought by consumers based upon personal injuries.

*Buckman v. Plaintiffs' Litigation Committee*, 531 U.S. 341 (2001), which is also heavily relied upon, is likewise distinguishable. As an initial matter, *Buckman* was not a pharmaceutical case but rather a medical products case which examined the issue of preemption specifically with regard to the Medical Device Amendment of the FDCA. It is important to note that complete preemption has not been found with respect to the FDCA. See *Wyeth v. Levine*, 129 S.Ct. 1187 (2009); *DeAngelo-Shuayto v. Organon USA Inc.*, 2007 WL 4365311 (D.N.J.). The Defendant concedes that the issue in *Buckman* concerned ordinary preemption as opposed to an examination of the "arising under" analysis used in the consideration of federal question jurisdiction which is the issue before this Court. Further stated, "*Buckman* does not make any holding with regard to the existence of federal question jurisdiction over a case by virtue of a state law claim that incorporates federal law as setting forth the standard of the offending conduct." *DeAngelo-Shuayto v. Organon USA Inc.*, 2007 WL 4365311 (D.N.J.). The

Defendant's reliance on *Grange v. Mylan Laboratories, Inc.*, 2008 WL 4813311 (D.Utah), *Kobar v. Novarits Corp.*, 378 F.Supp.2d 1166 (D.Ariz. 2006) and related authorities are misplaced for similar reasons.

Furthermore, the cases the Defendant cites in which federal jurisdiction was conveyed do not involve an individual personal injury action by a plaintiff alleging personal injuries as a result of the ingestion of a pharmaceutical product under the circumstances they claim in their present petition.

As a result, it is telling in the Defendant's papers in both responding to the Plaintiffs' original motion and its current objections, what is not cited. There are many personal injury lawsuits filed by plaintiffs each year alleging injuries caused by pharmaceutical products which, as cases like *Caggiano* make evident, have allegations which refer to the FDA and/or FDCA. The Defendant failed to cite one case in its prior arguments on this matter, and further fails to do so now, which a Court found federal question jurisdiction under the circumstances it attempts to espouse in this matter.

Rather, efforts similar to the ones made by the Defendant have been attempted before and rejected. The defendant in *Sullivan v. Novartis Pharmaceuticals Corp.*, 575 F.Supp.2d. 640 (D.N.J.), who also is a defendant in this case, attempted to make analogous arguments to the ones attempted by Defendant Astellas. In finding that federal jurisdiction should not be conveyed the Court in *Sullivan*, considered "that the federal issues potentially raised in the instant case are no more substantial than those raised in *Merrell Dow* and… the *Grable*'s Court's praise for *Merrell Dow*'s effect from protecting the federal system from a significant disturbance in the federal-state workload balance…" Id. at 650. See also *Sullivan v. Novartis*

*Pharmaceuticals Corp.*, 602 F.Supp.2d 527 (D.N.J. 2009) ("Defendant's argument in support of federal jurisdiction is not a novel one. To the contrary, it is one that has been repeatedly and uniformly rejected.")

The Report and Recommendation also properly considered the concerns set forth by *Grable* and other decisions, that extending federal jurisdiction in the manner purported by the Defendant would unduly disturb the balance between state and federal courts.

## CONCLUSION

Based on the above, Plaintiffs respectfully request an Order of this Court adopting the Report and Recommendation of Magistrate Judge Hugh B. Scott and remanding this action to the New York State Supreme Court, Erie County.

DATED: Lancaster, New York
November 6, 2009

S/Theresa M. Walsh
Theresa M. Walsh, Esq.
BROWN CHIARI, LLP
**Attorneys for Plaintiffs**
5775 Broadway
Lancaster, New York 14086
(716) 681-7190
twalsh@brownchiari.com

TO: Scott R. Jennette, Esq.
Sharon M. Porcellio, Esq.
WARD NORRIS, HELLER &
REIDY, LLP
**Attorneys for Defendant,**
**ASTELLAS PHARMA US INC.**
300 State Street, 6th Floor
Rochester, New York 14614
(585) 454-0737

Harvey L. Kaplan, Esq.

Mark C. Hagarty, Esq.
SHOOK, HARDY & BACON, LLP
**Attorneys for Defendant,**
**ASTELLAS PHARMA US INC.**
2555 Grand Boulevard
Kansas City, MO 64108
(202) 898-5800

cc: Susan A. Eberle, Esq.
BROWN & TARANTINO, LLC
**Attorneys for Defendants**
**PETER ACCETTA, M.D and**
**SUSAN M. PETERSON, RPA-C**
1500 Rand Building
14 Lafayette Square
Buffalo, NY 14203
(716) 849-6500

Harry F. Mooney, Esq.
HURWITZ & FINE, P.C.
**Attorneys for Defendant,**
**NOVARTIS PHARMACEUTICALS CORPORATION**
1300 Liberty Building
Buffalo, NY 14202
(716) 849-8900

Peter J. Skalaban, Jr., Esq.
Katherine R. Latimer, Esq.
SPRIGGS & HOLLINGSWORTH
**Attorneys for Defendant,**
**NOVARTIS PHARMACEUTICALS CORPORATION**
1350 I Street NW
Washington, DC 20005

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**CERTIFICATE OF SERVICE**
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I hereby certify that on November 6, 2009, I electronically Plaintiffs' Response to Defendant's Objections in the above captioned matter with the Clerk of the District Court using its CM/ECF system which would electronically notify the following CM/ECF participants: Scott R. Jennette, Esq.; Sharon M. Porcellio, Esq.; Harvey L. Kaplan, Esq.; Mark C. Hagerty, Esq.; Harry F. Mooney, Esq., Peter J. Skalaban Jr., Esq., and Katharine R. Latimer, Esq. and Susan A. Eberle, Esq.

DATED: November 6, 2009
Lancaster, New York

S/Theresa M. Walsh
Theresa M. Walsh Esq.
BROWN CHIARI, LLP
Attorneys for Plaintiffs
5775 Broadway
Lancaster, New York 14086
(716) 681-7190
twalsh@brownchiari.com